Claims 2, 16, 18, 29 and 41 have been canceled herein. Claims 1, 3-5, 14, 17, 19, 23-24, 28, 31, and 40 have been amended herein. No clams have been added herein. Therefore, claims 1, 3-15, 17, 19-28, 30-40 and 42-50 are under active consideration.

Claims 1-50 stand rejected under 35 U.S.C. 112, first paragraph, for "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." In support of the rejection, the Patent Office appears to contend that it would require undue experimentation to practice the invention as claimed. In particular, the Patent Office states the following:

> With respect to the "expert rules," Applicants argue that it is widely known and accepted that human knowledge about prediction and classification in any field can often be as a set of heuristics or "rules-of-thumb," therefore, would not require undue experimentaino which is found unpersuasive because the Applicants' response and the specification does not set forth the necessary disclosure that would support the Applicants' argument. As defined by the Encyclopedia Britannica, heuristic is branch of computer technology dealing with "trial-and-error" or "exploratory" method of problem-solving; involves taking certain steps toward solution of problem and evaluating results as these steps are completed; implies use of intuition instead of formal techniques; opposite of algorithmic approach, which is precisely defined and structured; comes from Greek word heuriskien, meaning "to find out, to discover." Therefore, a definition, which includes the phrases "trial-and-error," or "exploratory," conveys that heuristic is experimental in nature. A method which is inherently heuristic would require sufficient guidance and direction in formulating "expert rules" to enable a person of ordinary skill in the art to make and to use the invention without requiring undue experimentation.
>
> Applicants discuss the importance of references listed on pages 11-14 where a large number of diseases associated with a modified methylation pattern are identified. Therefore, it is assumed by the Applicant that because of the abundance of research literature

that one of ordinary skill in the art could use the information from the references, without undue experimentation, to devise expert rules for identifying a disease based on a methylation pattern. Such argument is also found unpersuasive because currently the art of identifying a disease based on a methylation pattern is comparable to one tossing a coin with a fifty percent chance to correctly determine, based on methylation pattern data, that a patient has myelodysplastic syndromes (MDS). According to the first reference on page 11, Aoki et al. cited a previous report by Uchida et al. that hypermethylation of the 5' CpG island of the $p15^{INK4B}$ gene occurred frequently in patients with MDS (16/32 [50%])(Page 1403, Column 1, Lines 12-13). Therefore, a method that is based on data that is at most fifty percent accurate would require sufficient guidance and direction in formulating "expert rules" to enable a person of ordinary skill in the art to make and to use the invention without requiring undue experimentation.

With respect to "selecting a type of disease or medical condition based on the methylation status...," and "ranked listing of diseases [...] based on the information about the methylation status [...]." Applicants argue that the disease types or medical conditions can be taken from any standard book for diagnosis on the basis of the methylation status which is found unpersuasive because diseases cited by references on pages 11-14, specifically Nosaka et al., used diagnostic criteria that are more than just methylation status. For example, leukemia is listed in the specification as one of the diseases that is found to be associated with methylation patterns. It has been reported that there are four clinical subtypes of adult T-cell leukemia-lymphoma and each subtype has its unique diagnostic criteria (Shimoyama M). The different set of criteria are critical for accurate T-cell leukemia-lymphoma diagnosis. Therefore, it is reiterated with respect to "selecting a type of disease or medical condition based on the methylation status...," and "ranked listing of diseases [...] based on the information about the methylation status," the instant application lacks any amount of direction as to the practice of the process of "selecting a type of disease or medical condition based on the methylation status..." The specification and response do not provide or suggest any parameters within which the selection is to be practiced, nor from which list the selection is being selected from. Further, the specification and argument do not provide or suggest any parameters within which the diagnostic criteria to each disease are being used in terms of ranking the disease. As such, claims drawn to the use of the select disease type or medical condition are not enabled.

Insofar as the foregoing rejection pertains to claims 2, 16, 18, 29 and 41, the foregoing rejection is moot in view of Applicants' cancellation herein of these claims. Insofar as the foregoing rejection pertains to claims 1, 3-15, 17, 19-28, 30-40 and 42-50, Applicants respectfully traverse the foregoing rejection.

The Patent Office is apparently contending that claims 1-50 are not enabled by the present specification because the specification allegedly lacks any amount or direction as to the processes of (1) generating "expert rules" for disease analysis; (2) "selecting a type of disease or medical condition based on the methylation status..."; and (3) "generating a ranked listing of diseases [...] based on the information about the methylation status...." Applicants respectfully disagree for at least the reasons below.

At the outset, Applicants note that the test of enablement is not whether experimentation is necessary, but rather, whether one of ordinary skill in the art, using the disclosure of the patent application together with information known in the art, would be able to make and use the claimed invention without requiring undue experimentation. Enablement is not precluded by the necessity for some experimentation so long as the amount of experimentation is not undue. The key word is "undue," not "experimentation."

Consequently, the determinative question to be asked in determining whether the claims meet the enablement requirement is whether there is sufficient guidance and direction in the application to enable a person of ordinary skill in the art to make and use the invention without requiring undue experimentation. Applicants respectfully contend that there is sufficient guidance and direction in the present case. Moreover, Applicants note that it is the Patent Office that bears the burden of proving that enablement is lacking; Applicants do not need to prove the specification is enabling

unless and until the Patent Office has made a prima facie case of non-enablement. Applicants respectfully submit that the Patent Office has not met its burden.

In any event, Applicants respectfully submit that the specification does provide sufficient guidance for a person of ordinary skill in the art to practice the present invention without requiring undue experimentation. As mentioned in the present specification (see, for example, pages 2-3), it is well-known that the modified expression of genes in a cell can lead to cancerous diseases. It is furthermore stated in the present specification that the most promising way of identifying transformed (e.g., malignant) cells is by examining the expression of as many genes (methylation sites) as possible at the same time (for example, by using chip technology). The same issue is addressed, albeit from a different angle, in item 3 of the specification, in which the cell is described as "a complex regulatory system." Again, it becomes clear from a reading of the present specification that a single piece of information is of little use for such a complex analysis, such as in the case of an analysis of gene expression in cell regulation. This is the reason why claim 1 of the present invention recites a "plurality of different methylation statuses."

This situation is then summarized in the chapter 7 of the present specification, in which it is first mentioned that before the invention, usually a "piece-by-piece" fashion was used in order to analyze gene expression and methylation. This is why it is stated at page 10, bottom, to page 11, top, of the specification that the information on pages 11 to 14 is given...only [to] indicate the widespread connection between modifications of the methylation patterns and human diseases."

Therefore, the guidance and direction for the person of ordinary skill in the art (which person would be highly skilled) might be summarized as follows:

a) given the advantages of a "pluralistic approach" to the expression profile analysis of cancer cells; and

b) given the disadvantages of the state of the art in analyzing only "piece-by-piece" which leads to the unpredictability of the results in the art; and, at the same time,

c) given the linkage between methylation and expression; and

d) given the linkage between modifications in the expression of a gene and disease of the cell;

e) then, a person of ordinary skill in the art would be taught and guided to develop expert rules by, first, collecting and taking into account all the above parameters a) to d) at the same time, and, second, to set up rules for a decision between either disease or no disease and the type of disease by putting together the above information in a "complex scenario approach."

Looking now at paragraph 6 of the outstanding Office Action in view of the above discussion, it can be seen that a person of ordinary skill in the art would be taught by the present specification that looking at one coin will not make any sense in the context of developing expert rules for methylation patterns that are disease specific. In developing these rules, the person of ordinary skill will not have to be inventive or use undue experimentation when taking and collecting together the information given in the specification, as the single elements that form the expert rules are given in the specification and/or are statistical methods known to the person of ordinary skill in the art. Thus, no undue experimentation is required.

Applicants respectfully submit that no heuristic approach will be involved. In fact, the "expert rules" must be, indeed, based on formal techniques (i.e., methylation analyses of several genes) and algorithmic approaches (i.e., as discussed in item 3., pages 5 to 6 of the specification, in

which it is taught to "classify cells and cell groups according to (methylation) states.) The fact that the current technology lacks precise information with respect to specific diseases and methylation is exactly why the inventors developed the present system, which overcomes the "coin tossing" situation.

With respect to paragraph 7 of the outstanding Office Action, a similar argument applies. In fact, an algorithmic approach is again applied when "selecting a type of disease or medical condition based on the methylation status...," and the "ranked listing." First, both terms do not mean that the selection has to be understood as an all-or-nothing selection. Otherwise, the generation of a ranked listing, as required by the present invention, would not make much sense. As is readily understood by a person of ordinary skill in the art, the selection will be made based on a variety of cut-off values that would result in a ranked listing of more or less likely disease states. The example of MDS (cited by the Patent Office) would therefore have a ranking of 50%. (It must be noted that the complex approach of the methylation data measurement will also overcome this "bad" quality value.)

Thus, several "fingerprints" of (possible) diseases with different rankings (qualities) will be generated based on the methylation statuses, and collected in the first knowledge base that is thus provided. The expert rules then simply have to provide for the best match of the methylation fingerprints (i.e., statuses) as newly analyzed with a given disease and to put out a ranked listing of diseases. There is no need to give a certain parameter for the selection to be practiced, as it is obvious that the quality of the diagnosis/match should always be as good as possible.

Nevertheless, it will increase the quality and flexibility of the overall decision to introduce a ranked listing, in which not only the best quality disease is displayed, as the selection is made from

a list that is constantly built up, that is, in which additional and yet unknown diseases and their complex methylation statuses are added. The list is made from the analyses as introduced in the first knowledge base, as this base is compared with the result of the sample to be analyzed. The list could contain information as provided in the publications as mentioned on pages 11-14 of the specification; nevertheless, these have to be seen in a complex fashion of analysis (as already stated above). That is why the invention will overcome the problems mentioned in the Nosaka paper cited by the Patent Office.

Accordingly, for at least the above reasons, the foregoing rejection should be withdrawn.

Claims 1-50 stand rejected under 35 U.S.C. 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." In support of the rejection, the Patent Office states the following:

> The rejection is maintained because Claims 1, 14, 28 and 40 are vague and indefinite for failing to recite a final process step, which agrees back with the preamble. For example, Claim 1 is drawn to a method for guiding the selection of a therapeutic treatment for a patient, yet the claim recites a final step of generating a list of diseases or medical conditions in a computing device. Also, a list of diseases or medical conditions does not agree with the goal of the preamble of accomplishing the step of selecting a single therapeutic treatment for a patient. Claim 14 is drawn to a method of treatment, yet, nowhere in the claim is the step of treating a patient is accomplished. The step of generating a ranked list of diseases or medical conditions may be a precursor step to treating a patient. However, generating ranked list of diseases or medical conditions does not actually accomplish the active step [of] treating a patient as administering a drug to address a specific disease or related symptoms would. Claims 28 and 40 are drawn to a system and a computer program for guiding the selection of a therapeutic treatment for a patient. Similar to Claims 1 and 14, these claims do not contain the support for achieving the goals of the preamble of guiding the selection of a therapeutic treatment for a patient because they merely recite ranked list of diseases or medical conditions. Thus, the instant

> claims are unclear as to whether the preamble of the actual claim steps control the metes and bounds of the claims. In other words, would someone infringe the claims by simply performing the claim steps without performing what the preamble states? Clarification of the metes and bounds of the claims via clearer claim wording is requested. Claims which are directly or indirectly dependent from claims 1, 14, 28 and 40 also contain the above unclarity due to their dependence.

Insofar as the foregoing rejection pertains to claims 2, 16, 18, 29 and 41, the foregoing rejection is moot in view of Applicants' cancellation herein of these claims. Insofar as the foregoing rejection pertains to claims 1, 3-15, 17, 19-28, 30-40 and 42-50, Applicants respectfully traverse the foregoing rejection.

Independent claim 1 has been amended herein to include the limitations of canceled claim 2. Consequently, claim 1 now recites, among other things, the step of generating in the computing device a ranked listing of available therapeutic treatment regimens. Such a step agrees back with the preamble, which recites a method for guiding the selection of a therapeutic treatment for a patient with a disease or medical condition.

Independent claim 14 has been amended herein to include the limitations of canceled claims 16 and 18. Consequently, claim 14 now recites, among other things, the step of providing said one or more specific treatment regimens to the patient. Such a step agrees back with the preamble, which recites a method for treating a patient with a disease or medical condition.

Independent claim 28 has been amended herein to include the limitations of canceled claim 29. Consequently, claim 28 now recites, among other things, means for generating in the computing device a listing or ranked listing of available therapeutic treatment regimens. Said means provides

support for achieving the goal of the preamble, which is to guide the selection of a therapeutic treatment regimen for a patient with a disease or medical condition.

Independent claim 40 has been amended herein to include the limitations of canceled claim 41. Consequently, claim 40 now recites, among other things, means for generating in said computing device a ranked listing of available therapeutic treatment regimens for said patient. Said means provides support for achieving the goal of the preamble, which is to guide the selection of a therapeutic treatment regimen for a patient with a disease or medical condition.

Accordingly, for at least the above reasons, the foregoing rejection should be withdrawn.

Claims 1, 2, 4 and 6-13 stand rejected under 35 U.S.C. 103(a) "as being unpatentable over Barry et al. (US PN 6081786) taken with Ben-Yehuda (December 1997)." In support of the rejection, the Patent Office argues that "Barry et al. discloses a method of providing patient information to a computing device that includes various knowledge bases" and that "Barry et al. teaches the selection of therapeutic treatment regimens for diseases (or medical conditions) such as cardiovascular disease, lung and prostate cancer, and organic brain syndrome." The Patent Office then goes on to state the following:

> However, Barry et al. does not specifically teach that the knowledge bases to comprise of methylation statuses at selected sites of the DNA in cells with a known disease or medical condition at selected sites of the DNA of a patient. Ben-Yehuda et al. teaches that methylation provides a better tool for monitoring the efficacy of IFNα treatment. Methylation analysis could pick up early signs of IFNα therapy failure and prompt an alternative mode of treatment, such as BMT (Page 4922, Column 2, Lines 22-26). Clearly, a skilled artisan would have been motivated to partake the concept emphasized by Barry et al. for providing patient information to a computing device that includes various knowledge bases by adding a knowledge base containing methylation statuses at selected sites of the DNA in cells with a known disease or medical condition at selected sites of the

> DNA of a patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to add patient data concerning patient methylation status and INFα treatment regimens provided by Ben-Yehuda et al. (Materials and Methods, Page 4919, Column 1 and 2) to the knowledge base of the method disclosed by Barry et al. for guiding the selection of therapeutic treatment regimens.

Insofar as the foregoing rejection pertains to claim 2, the rejection is moot in view of Applicants' cancellation herein of claim 2. Insofar as the foregoing rejection pertains to claims 1, 4 and 6-13, Applicants respectfully traverse the foregoing rejection.

The Patent Office is apparently contending (i) that Barry et al. teaches all of claim 1, except for "knowledge bases [comprising] methylation statuses at selected sites of the DNA in cells with a known disease or medical condition at selected sites of the DNA of a patient"; (ii) that Ben-Yehuda et al. teaches "that methylation provides a better tool for monitoring the efficacy of IFNα treatment"; and (iii) that it therefore would have been obvious to one of ordinary skill in the art "to add patient data concerning patient methylation status and INFα treatment regimens provided by Ben-Yehuda et al. to the knowledge base of the method disclosed by Barry et al. for guiding the selection of therapeutic treatment regimens." For at least the reasons below, Applicants respectfully disagree with the Patent Office's conclusion of obviousness.

First, Applicants respectfully submit that the applied references, even if combined in the manner proposed by the Patent Office, do not teach or suggest the claimed invention. More specifically, the applied references, taken together or individually, do not teach or suggest the diagnosing of an unknown disease (i.e., generating in a computing device a listing or ranked listing of diseases or medical conditions). Barry et al. is limited to teaching systems, methods and computer program products for guiding the selection of a therapeutic treatment regimen for a known (i.e.,

already diagnosed) disease, such as HIV. Barry does not in any way involve the diagnosis of an unknown (i.e., yet-to-be diagnosed) disease. Ben-Yehuda et al., which is limited to describing a "piece-by-piece" analysis of the methylation of the CML specific promoter *abl*, is not in any way involved in the diagnosis of a disease (since the patients have already been diagnosed with CML).

Second, there is no basis for combining the references in the manner proposed by the Patent Office. More specifically, nothing in the references would have provided any motivation to a person of ordinary skill in the art to combine the references as suggested.

Third, as stated on page 8 of the present specification, the sensitivity of the type of method used by Ben-Yehuda, namely, methylation specific digestion, is low, despite the use of PCR. Thus, Ben-Yehuda teaches that the methylation analysis of *abl* might give additional support, but will not serve as the basis for drawing a decision for a) the type of disease involved, and b) the type of therapy to be used. Furthermore, Ben-Yehuda is silent about the inclusion of additional methylation analyses outside of *abl* in order to increase the accuracy of diagnosis. In fact, the analysis of the present invention requires a "plurality" of different methylation statuses. Ben-Yehuda analyzes five sites on one promoter. Finally, only the result of the treatment with IFNα is monitored, i.e., of a singular treatment regimen.

Accordingly, for at least the above reasons, the foregoing rejection should be withdrawn.

Applicants note that claims 3, 5, 14-15, 17, 19-28, 30-40 and 42-50 have not been rejected on the basis of any art. Accordingly, in view of the fact that the outstanding rejections under 35 U.S.C. 112 should be withdrawn for at least the reasons given above, claims 3, 5, 14-15, 17, 19-28, 30-40 and 42-50 should be allowed immediately.

It is respectfully submitted that the present application is in condition for allowance. Prompt and favorable action is earnestly solicited.

If there are any fees due in connection with the filing of this paper that are not accounted for, the Examiner is authorized to charge the fees to our Deposit Account No. 11-1755. If a fee is required for an extension of time under 37 C.F.R. 1.136 that is not accounted for already, such an extension of time is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Dated: May 14, 2003

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 14, 2003

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Dated: May 14, 2003

MARKED-UP AMENDED CLAIMS 1, 3-5, 14, 17, 19, 23-24, 28, 31 AND 40

1. (Amended) A method for guiding the selection of a therapeutic treatment regimen for a patient with a disease or medical condition, said method comprising:

(A) providing information about the methylation status at selected sites of the DNA of the patient to a computing device comprising:

a first knowledge base comprising information about a plurality of different methylation statuses at selected sites of the DNA in cells with a known disease or medical condition and/or healthy cells,

a second knowledge base comprising a plurality of expert rules for evaluating and selecting a type of disease or medical condition based on the methylation status at selected sites of the DNA of a patient,

a third knowledge base comprising a plurality of different therapeutic regimens for diseased cells or medical conditions,

a fourth knowledge base comprising a plurality of expert rules for evaluating and selecting therapeutic treatment regimens for diseased cells or medical conditions,

(B) generating in said computing device a listing or ranked listing of diseases or medical conditions based on the information about the methylation status at selected sites of the DNA of the patient, the first knowledge base and the second knowledge base, and

(C) generating in said computing device a ranked listing of available therapeutic treatment regimens for said patient based on the information generated in step (B) and the third knowledge base and fourth knowledge base.

3. (Amended) A method according to claim [2] 1, characterized in that the therapeutic regimen is a preventive therapeutic treatment regimen.

4. (Amended) A method according to claim [2] 1, further comprising:

a fifth knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens; and

(D) generating in said computing device advisory information for one or more treatment regimens in said ranked listing based on the information generated in step (C) according to claim [2] 1 and the fifth knowledge base.

5. (Amended) A method according to claim [2] 1, further comprising the steps of:

(E) entering a user-defined therapeutic treatment regimen for said disease or medical condition that is not included in said third knowledge base; and

(F) generating in said computing device advisory information for one or more user-defined combination therapeutic treatment regimen.

14. (Amended) A method for treatment of a patient with a disease or medical condition, said method comprising:

(A) isolating a DNA-containing sample from said patient;

(B) analyzing cytosine methylation patterns at selected sites of the DNA contained in said sample;

(C) providing data about the methylation status at selected sites of the DNA of the patient thereby creating a first knowledge base comprising said data, a second knowledge base comprising information about a plurality of different methylation statuses at selected sites of the DNA in cells with a known disease or medical condition and/or healthy cells, a third knowledge base

comprising a plurality of expert rules for evaluating and selecting a type of disease or medical condition based on the methylation status at selected sites of the DNA of a patient, [and] a fourth knowledge base comprising a plurality of different therapeutic regimens for diseased cells or medical conditions, a fifth knowledge base comprising a plurality of expert rules for evaluating and selecting therapeutic treatment regimens for diseased cells or medical conditions, a sixth knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens;

(D) generating a ranked listing of diseases or medical conditions based on the data of the first knowledge base, the second knowledge base and the third knowledge base;

(E) generating a ranked listing of available therapeutic treatment regimens for said patient based on the information generated in step (D) and the fourth knowledge base and the fifth knowledge base;

(F) generating advisory information for one or more specific treatment regimens in said ranked listing based on the information generated in step (E) and the sixth knowledge base; and

(G) providing said one or more specific treatment regimens to said patient with a disease or medical condition based on the advisory information generated in step (F).

17. (Amended) A method according to claim [16] 14, characterized in that the therapeutic treatment regimen is a preventive treatment regimen.

19. (Amended) A method according to claim [16] 14, further comprising the steps of:

(H) entering a user-defined therapeutic treatment regimen for said disease or medical condition that is not included in said fourth knowledge base; and

(I) generating advisory information for one or more user-defined combination therapeutic treatment regimen.

23. (Amended) A method according to claim [18] 14, said advisory information including:

warnings to take the patient off a contraindicated drug before initiating a corresponding therapeutic treatment regimen; and information clinically useful to implement a corresponding therapeutic treatment regimen.

24. (Amended) A method according to claim [18] 14, comprising a seventh knowledge base comprising patient therapeutic treatment regimen history, said advisory information including previous therapeutic treatment regimen information extracted from said seventh knowledge base.

28. (Amended) A system for guiding the selection of a therapeutic treatment regimen for a patient with a disease or medical condition, said system comprising:

(A) a computing device comprising:

a first knowledge base comprising information about a plurality of different methylation statuses at selected sites of the DNA in cells with a known disease or medical condition and/or healthy cells,

a second knowledge base comprising a plurality of expert rules for evaluating and selecting a type of disease or medical condition based on the methylation status at selected sites of the DNA of a patient,

a third knowledge base comprising a plurality of different therapeutic regimens and/or preventive therapeutic treatment regimens for diseased cells or medical conditions,

a fourth knowledge base comprising a plurality of expert rules for evaluating and selecting therapeutic treatment regimens for diseased cells or medical conditions;

(B) means for providing information about the methylation status at selected sites of the DNA of the patient to computing device;

(C) means for generating in said computing device a ranked listing of diseases or medical conditions based on the information about the methylation status at selected sites of the DNA of the patient, the first knowledge base and the second knowledge base; and

(D) means for generating in said computing device a listing or ranked listing of available therapeutic treatment regimens for said patient based on the information generated according to step (C), the third knowledge base and the fourth knowledge base.

31. (Amended) A system according to claim [29] 28, further comprising:

(F) means for entering a user-defined therapeutic treatment regimen for said disease or medical condition that is not included in said third knowledge base; and

(G) means for generating in said computing device advisory information for one or more user-defined combination therapeutic treatment regimen.

40. (Amended) A computer program product for guiding the selection of a therapeutic treatment regimen for a patient with a disease or medical condition, said computer program product comprising

a computer usable storage medium having computer readable program code means embodied in the medium, the computer readable program code means comprising:

(A) computer readable program code means for generating:

a first knowledge base comprising information about a plurality of different methylation statuses at selected sites of the DNA in cells with a known disease or medical condition and/or healthy cells,

a second knowledge base comprising a plurality of expert rules for evaluating and selecting a type of disease or medical condition based on the methylation status at selected sites of the DNA of a patient,

a third knowledge base comprising a plurality of different therapeutic regimens and/or preventive therapeutic regimens for diseased cells or medical conditions,

a fourth knowledge base comprising a plurality of expert rules for evaluating and selecting therapeutic treatment regimens for diseased cells or medical conditions,

a fifth knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens; [and]

(B) computer readable program code means for providing information about the methylation status at selected sites of the DNA of the patient;

(C) computer readable program code means for generating a ranked listing of diseases or medical conditions based on the information about the methylation status at selected sites of the DNA of the patient; [and]

(D) computer readable program code means for generating in said computing device a ranked listing of available therapeutic treatment regimens for said patient; and

(E) computer readable program code means for generating in said computing device advisory information for one or more treatment regimens in said ranked listing.